



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/284,421	06/11/1999	JOHN FRANCIS GORDON	043601/0110	2286
20995	7590	02/27/2007	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			WALLENHORST, MAUREEN	
			ART UNIT	PAPER NUMBER
			1743	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	02/27/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 02/27/2007.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)
	09/284,421	GORDON, JOHN FRANCIS
	Examiner	Art Unit
	Maureen M. Wallenhorst	1743

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 02 February 2007.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 89-99, 105, 107, 108, 110-123, 125-131 and 156-158 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 89-99, 105, 107, 108, 110-123, 125-131 and 156-158 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1743

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 2, 2007 has been entered.

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

3. Claims 90-91, 105, 107-108, 110-123, 125-131, and 157-158 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

On line 1 of claims 90 and 91, the phrase "the spacing" lacks antecedent basis since this phrase has been deleted from independent claim 89.

On line 11 of claim 105, the phrase "at least one insert position within" should be changed to –at least one insert positioned within—in order to make proper sense. On line 15 of claim 105, the phrase "said plurality of surface locations" lacks antecedent basis since a positive recitation of the surface locations has been deleted from claim 105.

On line 2 of claim 107, the phrase "said locations" lacks antecedent basis.

In claim 110, the phrase "said plurality of surface locations" lacks antecedent basis.

On lines 2-3 of claim 116, the phrase "the surface locations" lacks antecedent basis.

Claim 117 is indefinite since it is not clear whether the inserts are received in the one or more chambers of the device recited in claim 105. Where are the inserts located in the structure of claim 105? In addition, claim 117 is indefinite since independent claim 105 already recites an

insert in the device. Therefore, claim 117 is repetitive with claim 105 and does not further limit claim 105.

On line 2 of claim 119, the phrase “the disc” lacks antecedent basis since claim 119 depends from claim 117, not 118. See this same problem with the phrase “the disc” in claim 120.

On line 2 of claim 121, the phrase “said surface locations” lacks antecedent basis. Claim 121 is also indefinite since it is not clear where in the structure the one more lenses are located.

Claim 123 is indefinite since it is not clear where in the assay plate structure the at least one insert disc is located. Is the insert disc located in the space between the upper and lower surfaces?

In claim 125, the phrase “said at least one first opening” lacks antecedent basis since the recitation of the at least one first opening has been deleted from independent claim 123.

In claim 127, the recitation of the “at least one second opening” is indefinite since independent claim 123 fails to positively recite at least one first opening.

On line 3 of claim 128, the phrase “said first openings” lacks antecedent basis.

In claim 157, the phrase “the surface locations bearing a hydrophilic coating” lacks antecedent basis since claim 105, from which claim 157 depends, fails to positively recite surface locations.

On line 2 of claim 158, the phrase “said fluid” lacks antecedent basis since independent claim 123 fails to positively recite any fluid in the claim.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 1743

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 89-99, 105, 107-108, 110-117, 121-123, 125-131 and 156-158 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelton et al (US Patent no. 5,496,520, cited previously) in view of Gordon (WO 96/09548, cited previously).

Kelton et al teach of a rotary fluid manipulator that is used to perform different types of diagnostic assays such as immunoassays. The device comprises a two part housing 12 consisting of an upper, substantially planar, rigid surface 14 and a lower, substantially planar, rigid surface 16. Located between the upper and lower surfaces is a body or insert 20 that is impregnated with different reagents such as antigens and antibodies for reacting with a sample fluid. The body 20 is divided into a plurality of sections 26 so that a separate assay may be accomplished in each of the sections. Radial slots 28 define each of the sections 26 and prevent fluid from migrating into adjacent sections 26. The upper and lower surfaces 14 and 16 are connected to one another with a space there between holding the body 20. The upper portion 14 is superimposed over the lower portion 16 using corresponding alignment slots and bosses 44, 46. Locating ribs 38 on the lower portion serve to fit into radial slots 28 on the insert 20. The locating ribs 38 serve as walls to

subdivide the insert disc 20 into a plurality of separate spaces 26. An enlarged central opening or aperture 50 is located in the planar, rigid surface of upper surface 14 that serves as an eluant dosing aperture to permit eluant to be fed into an eluant receiving area 24 on the body 20. In addition, the upper surface contains a plurality of specimen dosing orifices 52 which permit specimens to be applied to the different sections 26 in the body 20 that are separated from one another by the ribs or walls 38. With the device taught by Kelton et al, the specific reagents (i.e. antibodies and antigens) to be reacted on a disc structure are kept isolated from the outside environment by the upper and lower surfaces 14, 16, and a central opening 50 in the upper surface is used for dispensing reagents to the reactants on the disc structure. Kelton et al teach that the upper and lower sections of the housing are made from transparent materials, and that the reactions between the antigens and antibodies in each of the separate sections 26 in the device can be measured using various types of light sources or photodetectors. See Figures 1-3, lines 59-67 in column 3, lines 33-63 in column 4, lines 26-39 and 59-67 in column 5 and lines 1-51 in column 6 of Kelton et al. Kelton et al fail to teach that one of the upper or lower surfaces 14 or 16 contains encoded information therein that includes address location information as to the part of the structure being scanned by a light beam, fail to teach of at least one opening in the peripheral edge of the device and fail to teach that the device can have one reflecting surface therein.

Gordon teaches of an apparatus for conducting the optical inspection of a biological, chemical or biochemical sample supported on an optically transparent disc. The apparatus comprises a substrate having a surface for supporting a sample, a source of electromagnetic radiation for providing a beam of electromagnetic radiation, a means for scanning the beam

Art Unit: 1743

across the surface of the substrate, and a detector means arranged to detect electromagnetic radiation reflected and/or transmitted through the substrate, wherein the substrate is provided with digitally encoded information thereon that is scanned by the beam of electromagnetic radiation and that contains information indicative of the address or location on the surface of the substrate which the beam is currently directed. The detector means is arranged to decode the electromagnetic radiation beam to determine the encoded address and to determine if the received beam has been modulated by any of the sample on the substrate. The provision of address information in or on the substrate enables the precise position of the electromagnetic radiation beam on the surface to be determined which in turn allows the accurate mapping of optical data, corresponding to attached material, on the surface. The substrate is provided in the form of a circular disc 1 that has a surface for supporting a sample and a surface with a plurality of perturbations that represent the digitally encoded data. The disc 1 comprises upper and lower layers of transparent plastic 2, 3, with a reflective layer sandwiched in-between. A lens arrangement 10 is located on the disc structure. In the embodiment depicted in Figure 6 of Gordon, the disc 44 comprises a plurality of wells or indentations 51 formed in its upper surface. The wells contain different samples to be inspected. Gordon also teaches that it is possible to construct the disc in such a way that the support surface is internal to the disc and is not the upper surface of the disc. This provides the advantages that the sample is not damaged by handling and that a precise volume of sample is analyzed. See pages 3-4, 7, 10, 12, 14 and 22-23 of Gordon. Gordon qualifies as a reference under 35 USC 102(b) since it was published on March 28, 1996, which is more than one year from the effective filing date of the instant application (i.e. August 10, 1997).

Based upon the combination of Kelton et al and Gordon, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to provide one of the upper or lower surfaces in the rotary fluid manipulator taught by Kelton et al with encoded address information readable by a scanned light beam since Kelton et al teach that a light beam can be used to measure the reactions between antibodies and antigens on the insert 20, and Gordon teaches that the provision of encoded address information on an assay plate device enables the precise position of an electromagnetic radiation beam on the surface of the plate to be determined which in turn allows the accurate mapping of optical data, corresponding to attached material, on the surface. It also would have been obvious to one of ordinary skill in the art to provide at least one opening in the peripheral edge of the rotary fluid manipulator taught by Kelton et al so as to provide a means of venting air from the device in order to facilitate the movement of liquid into the sections 26 on the insert 20 from the openings 50 and 52 in the upper surface of the device. It also would have been obvious to one of ordinary skill in the art to provide a reflecting surface in the device taught by Kelton et al in addition to the transparent surfaces since Gordon teaches that optical discs for analyzing biological, chemical or biochemical samples have improved signal detection from the reagents/samples on the disc when both a transparent and a reflective surface is provided in the disc.

7. Claims 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelton et al in view of Gordon as applied to claims 89-99, 105, 107-108, 110-117, 121-123, 125-131 and 156-158 above, and further in view of Merkh et al (US Patent no. 5,281,540, cited previously). For a teaching of Kelton et al and Gordon, see previous paragraphs in this Office action. Kelton et al fail to teach that the insert 20 can be divided into separate physical sectors of the disc.

Merkh et al teach of a disc structure 18, which is divided into sector inserts 80 comprising wells 84. The system of Merkh et al includes a liquid injecting device 31, which penetrates the self-sealing cover 90 of each sector at port 92 (see column 10, lines 1-7). The sector inserts 80 and the disc 18 include locks 100, 102, 104 and key 93 portions to allow the sectors to be snap-fitted in the correct orientation on the disc 18. Additionally, the disc comprises a plurality of dividing walls 131.

Based upon the combination of Kelton et al, Gordon and Merkh et al, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to divide the insert 20 taught in the rotary fluid manipulator device of Kelton et al into physically separate sections of the disc, similar to the sector inserts 80 taught by Merkh et al, in order to better accommodate multiple different samples on the sections 26 of the Kelton et al disc for analysis at the same time with better assurance that the samples will not migrate into one another and contaminate adjacent samples.

8. Applicant's arguments with respect to claims 89-99, 105, 107-108, 110-123, 125-131 and 156-158 have been considered but are moot in view of the new ground(s) of rejection.

The previous grounds of rejection of the claims under 35 USC 112, second paragraph made in the last Office action mailed on January 6, 2006 have been withdrawn in view of Applicant's amendments to the claims. However, new grounds of rejection of the amended claims under this statute are set forth above, as necessitated by Applicant's amendments to the independent claims with no corresponding amendments to the dependent claims.

Although the grounds of rejection for the claims under 35 USC 103 have changed in this Office action, the same references as used previously are used in the new rejections, and therefore, the Examiner responds to Applicant's arguments below.

Applicant argues that neither reference to Gordon or Kelton et al teach of the limitation of a cavity between the upper and lower substantially planar surfaces holding an insert disc having a plurality of separate reaction sites. However, it is noted that the reference to Kelton et al, which has now been applied as the primary reference in the rejection of the claims under 35 USC 103, does teach of a device having an upper substantially planar rigid surface (upper surface 14), a lower substantially rigid planar surface (lower surface 16), wherein a cavity is formed between the upper surface 14 and the lower surface 16 when the surfaces are joined together, and an insert disc 20 held in the cavity between the surfaces 14 and 16. The insert disc 20 taught by Kelton et al includes a plurality of reaction sites 26 having antibodies thereon. See Figure 3 in Kelton et al.

Applicant also argues that the Examiner's conclusory findings regarding the motivation to combine the references is based upon impermissible hindsight. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Applicant also argues that there is no common problem among the references applied under 35 USC 103 that would motivate their combination. In response to this argument, it is noted that all three reference to Kelton et al, Gordon and Merkh et al teach of plate-like or disc-like devices holding multiple samples thereon for optical analysis. Therefore, each of these references have the common problems of keeping the samples separate from one another, allowing a light source to properly analyze the samples, and knowing which optical measurements correspond to which samples on the plate or disc. Motivation to incorporate the encoded information on the disc taught by Gordon with the disc taught by Kelton et al comes from the teaching of Gordon concerning encoded address information on an assay plate device enabling the precise position of an electromagnetic radiation beam on the surface of a plate being determined which in turn allows the accurate mapping of optical data, corresponding to attached material, on the surface. Motivation to physically separate the disc insert 20 taught by Kelton et al into individual sectors of the disc comes from the teaching of Merkh et al that individual sectors of a disc allow multiple different samples to be accommodated in a rotary-type apparatus at the same time with assurance that the samples will not migrate into one another and contaminate adjacent samples.

Applicant also argues that the combination of references would change the principle of operation of the devices in each of the references. For example, Applicant argues that Merkh et al operates on the principle of diffuse reflectance to read test results from the test sites, whereas Gordon operates by transmitting light through the disc. In response to this argument, it is noted that Gordon also teaches of measuring light reflected by the disc. See lines 26-28 on page 2 and lines 14-17 on page 3 of Gordon where it states that a detector detects radiation reflected from

and/or transmitted through the substrate. In addition, Applicant argues that in Merkh et al, waste is removed from the sectors of the disc through a probe inserted through a non-rigid cover, whereas the device taught by Kelton et al has a rigid permanent lid, and Gordon fails to teach washing during rotation of the disc. In response to this argument, it is noted that the washing steps taught by Merkh et al would not change the principle of operation of the Kelton et al device since a probe can be inserted into the opening 50 in the device of Kelton et al if so desired to dispense a washing agent. It is noted that the primary reference relied upon in rejecting the claims now is Kelton et al, and the principle of operation of the Kelton et al optical disc device would not change by incorporating the encoded address information taught by Gordon into the optical disc or by separating the insert 20 in the Kelton et al device into physically separate sectors, as taught by Merkh et al.

For all of the above reasons, Applicant's arguments are not found persuasive.

Art Unit: 1743

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Thursday from 6:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst
Primary Examiner
Art Unit 1743

mmw

February 13, 2007

Maureen m. Wallenhorst
MAUREEN M. WALLENHORST
PRIMARY EXAMINER
GROUP 1700